



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3264-PN]

#### **Medicare and Medicaid Programs; Application by American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for Continuing CMS-approval of its Ambulatory Surgery Center (ASC) Accreditation Program**

**AGENCY:** Centers for Medicare and Medicaid Services (CMS), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for continued recognition as a national accrediting organization for ambulatory surgery centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[insert date 30 days after date of publication in the Federal Register]**.

**ADDRESSES:** In commenting, refer to file code CMS-3264-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3264-PN,  
P.O. Box 8016,  
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3264-PN,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments before only to the following addresses:

a. For delivery in Washington, DC--  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the section entitled **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Barbara Easterling, (410) 786-0416, Patricia Chmielewski, (410) 786-6899 or Cindy Melanson, (410) 786-0310.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been

received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## **I. Background**

Section 1865(a)(3)(A) of the Social Security Act (the Act), requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period. Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832 (a)(2)(F)(i) of the Act establishes distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, in order to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416.

Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether

it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §488.4 and §488.8(d)(3). The regulations at §488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The American Osteopathic Association/Healthcare Facilities Accreditation Program's (AOA/HFAP) current term of approval for their ASC accreditation program expires October 23, 2012.

## **II. Approval of Deeming Organizations**

Section 1865(a)(2) of the Act and our regulations at §488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider,

among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and, ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AOA/HFAP's request for continued approval of its ASC accreditation program. This notice also solicits public comment on whether AOA/HFPA's requirements meet or exceed the Medicare conditions for coverage for ASCs.

### **III. Evaluation of Deeming Authority Request**

AOA/HFAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its ASC accreditation program. This application was determined to be complete on March 27, 2012. Under Section 1865(a)(2) of the Act and our regulations at §488.8 (Federal review of accrediting organizations), our review and evaluation of AOA/HFAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AOA/HFAP's standards for an ASC as compared with CMS' ASC conditions for coverage.

- AOA/HFAP's survey process to determine the following:
  - + The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- + The comparability of AOA/HFAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- AOA/HFAP's processes and procedures for monitoring an ASC found out of compliance with AOA/HFAP's program requirements. These monitoring procedures are used only when AOA/HFAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at §488.7(d).

- AOA/HFAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- AOA/HFAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- The adequacy of AOA/HFAP's staff and other resources, and its financial viability.

- AOA/HFAP's capacity to adequately fund required surveys.

- AOA/HFAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

- AOA/HFAP's agreement to provide CMS with a copy of the most current accreditation survey, together with any other information related to the survey as we may require (including

corrective action plans).

#### **IV. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

#### **V. Response to Public Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “**DATES**” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.



CMS-3264-PN

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare--Ambulatory surgery center Insurance Program; and No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 16, 2012

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**Marilyn Tavenner,**

Acting Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

CMS-3264-PN

**[FR Doc. 2012-12823 Filed 05/24/2012 at 8:45 am; Publication Date: 05/25/2012]**